

Exhibit DD

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Michelle Simha, as Trustee for the
Next-of-Kin of Noah Leopold,

Plaintiff,

vs.

Mayo Clinic,

Defendant.

Civil File No. 24-CV-01097-JRT-DTS

**DEFENDANT MAYO CLINIC'S
OBJECTIONS AND RESPONSES
TO PLAINTIFF'S FIRST SET OF
REQUESTS FOR PRODUCTION**

To: Plaintiff Michelle Simha, and her attorney, Brandon E. Thompson, Ciresi Conlin LLP, 225 South Sixth Street, Suite 4600, Minneapolis, MN 55402.

Defendant Mayo Clinic ("Mayo"), by and through its counsel, and pursuant to Federal Rule of Civil Procedure 34, hereby submits the following objections and responses to Plaintiff Michelle Simha's First Set of Requests for Production to Defendant Mayo Clinic ("Requests").

GENERAL OBJECTIONS

1. Mayo objects to Plaintiff's Requests, and the corresponding instructions, to the extent they seek to impose obligations beyond those required by the Federal Rules of Civil Procedure.

2. Mayo objects to Plaintiff's Requests to the extent they seek documents subject to the attorney-client privilege, work product doctrine, or any other applicable privilege or protection. In responding to any request, Mayo does not waive its right to assert any privilege or protection.

3. Any inadvertent production by Mayo shall not constitute a waiver of any such privilege or protection. Mayo reserves the right to request the return of any non-discoverable document that is inadvertently produced.

4. Mayo objects to the instruction contained in Plaintiff's Requests concerning "Lost or Destroyed Documents" which seeks information about any responsive document that "has been lost or destroyed." This Instruction seeks information, rather than documents, and is not permitted under Fed. R. Civ. P. 34.

5. Mayo objects to Plaintiff's definitions of "You," "Your," "Yours," and "Defendant" insofar as they purport to include undefined "related entity (association, corporation, partnership, including any variation or form of same); related individual (partner, agent, employee, or contractor); or representative (attorney, insurance company or any person employed by same)." Mayo will respond to Plaintiff's Requests by producing reasonably accessible documents within Mayo's possession, custody, or control as required by the Federal Rules of Civil Procedure, the Court's orders, and/or the parties' agreements.

6. Mayo objects to Plaintiff's definition of "Identify" insofar as it purports to seek information, rather than documents, which is not permitted under Fed. R. Civ. P. 34. Mayo will respond to Plaintiff's Requests by producing reasonably accessible documents within Mayo's possession, custody, or control as required by the Federal Rules of Civil Procedure, the Court's orders, and/or the parties' agreements

7. Mayo objects to Plaintiff's definition of "Facility" insofar as it purports to include undefined "divisions or sub-parts thereof." Mayo will respond to Plaintiff's Requests by producing reasonably accessible documents

within Mayo's possession, custody, or control as required by the Federal Rules of Civil Procedure, the Court's orders, and/or the parties' agreements.

8. Mayo objects to Plaintiff's definitions of "Possession, Custody and Control" insofar as it purports to include undefined "right[s] (superior to that of the requesting party) to compel the production from a third party entity (including an agency, subsidiary, division, authority or representative) having physical possession of the item." Mayo will respond to Plaintiff's Requests by producing reasonably accessible documents within Mayo's possession, custody, or control as required by the Federal Rules of Civil Procedure, the Court's orders, and/or the parties' agreements.

9. Mayo continues to gather information and reserves the right to supplement, revise, correct, clarify, or amend any of the following answers.

10. Nothing herein shall be construed as an admission as to the relevance or admissibility of any information or documents produced in response to Plaintiff's Requests.

11. Each of Mayo's answers to Plaintiff's Requests is subject to these general objections as well as the objections made in response to each particular Request. By responding to certain of Plaintiff's Requests, Mayo does not waive these general objections or any specific objections to a particular Request.

12. Counsel for Mayo invite discussion with counsel for Plaintiff with respect to objections and responses to Plaintiff's Requests, with the expectation that discussion between counsel may lead to elimination or modification of objections, reduce burdens on the parties, or otherwise result in mutually-satisfactory resolution of asserted objections

13. As set forth below, Mayo's production of certain documents is contingent upon entry by the Court of a mutually-agreeable protective order. A proposed protective order is attached as Exhibit A.

RESPONSES TO REQUESTS FOR PRODUCTION

REQUEST NO. 1: Medical records: Please produce a complete, organized, paginated copy of all medical records in your possession for Noah Leopold, including all imaging studies.

Plaintiffs' counsel is in possession of many records, but wants to ensure all parties are working from the exact same set of medical records. This is an ongoing request. If at any point in this litigation you receive additional medical records, from any source, please produce a copy so the parties can be assured that everyone is working with the same medical records. To the extent records in your possession have already been produced to or exchanged by the parties, you need not provide those records. This Request is designed to gather only those records that have not already been produced.

RESPONSE: Mayo objects to this request as overly broad, unduly burdensome, and disproportionate to the needs of the case. Mayo further objects to the extent that this request is not limited in time.

Subject to and without waiving the foregoing general and specific objections, Mayo will produce Noah Leopold's Mayo medical records, including any medical imaging related to the treatment in question.

REQUEST NO. 2: Cardiac pathology slides: Please produce recut slides, with H&E stains, from each tissue block taken from both the August 29 Donor Heart and Noah Leopold's native heart. This includes, but is not limited to, the blocks taken and/or examined as part of the surgical pathology report identified as follows:

APFS

Subject to and without waiving the foregoing general and specific objections, and following entry of a mutually-agreeable protective order, Mayo will produce documents not protected from disclosure that are responsive to this request.

REQUEST NO. 4: Informed consent documentation: Please produce, separately from the tens of thousands of pages of medical records you will produce in response to Request #1, a copy of any and all documents you claim evidence an informed consent discussion with Noah Leopold. By this Request, Plaintiff intends to determine precisely which portions of the medical record you claim document any informed consent discussion that was had with Noah Lepold by any Mayo agent or employee at any time.

RESPONSE: Mayo objects to this request as overly broad, unduly burdensome, disproportionate to the needs of the case, and vague insofar as the term “informed consent discussion” is not defined. Mayo also objects to this request to the extent it seeks to impose obligations beyond those required by Fed. R. Civ. P. 34. Mayo further objects to this request to the extent it is an improper contention request.

Subject to and without waiving the foregoing general and specific objections, Mayo refers Plaintiff to Noah Leopold’s Mayo medical records. Mayo further states it is not presently aware of any other documents responsive to this request. Discovery is ongoing and Mayo reserves the right to supplement or amend this response.

REQUEST NO. 5: OCS Heart informed consent documentation: Please produce, separately from the tens of thousands of pages of medical records you will produce in response to Request #1, a copy of any and all documents you claim evidence any discussions Mayo agents/employees had with Noah Leopold about the risks and benefits of accepting a heart that would be transported using the OCS Heart, as well as any discussions about the alternatives to accepting a heart that would be transported using the OCS Heart.

RESPONSE: Mayo objects to this request as overly broad, unduly burdensome, disproportionate to the needs of the case, and vague insofar as the term “informed consent documentation” is not defined. Mayo also objects to this request to the extent it seeks to impose obligations beyond those required by Fed. R. Civ. P. 34. Mayo further objects to this request to the extent it is an improper contention request.

Subject to and without waiving the foregoing general and specific objections, Mayo refers Plaintiff to Noah Leopold’s Mayo medical records. Mayo further states it is not presently aware of any other documents responsive to this request. Discovery is ongoing and Mayo reserves the right to supplement or amend this response.

REQUEST NO. 6: Photographs, slides, and videotapes: Please produce any photographs, slides, videotapes and/or motion pictures and/or digital images which relate or depict the following:

- a. Any aspect of your care and treatment of Mr. Leopold;
- b. The condition of Mr. Leopold before and/or after the occurrence in question;
- c. The condition of the August 29 Donor Heart at any time, including but not limited to before procurement, after procurement, before it was placed on the OCS Heart, while it was on the OCS Heart, after it was taken off the OCS Heart at Mayo, pre-, intra- and post- attempted transplant, and on pathology.
- d. Concerning in any manner whatsoever the incident in question;

RESPONSE: Mayo objects to this request as overly broad, unduly burdensome, and disproportionate to the needs of the case. Mayo further objects to this request to the extent it seeks protected health information or other information protected from disclosure by applicable law, contractual obligations,

and/or obligations imposed on Mayo by non-Mayo entities, including without limitation CMS, UNOS, and TransMedics, Inc.

Subject to and without waiving these objections, Mayo refers Plaintiff to Noah Leopold's Mayo medical records. Following entry of a mutually-agreeable protective order, Mayo will produce additional documents not protected from disclosure that are responsive to this request.

REQUEST NO. 7: Your bill: Please produce the following documents concerning your bill for professional services rendered and medical and drug products furnished to Mr. Leopold:

- a. Itemized bill or itemized statement of fees;
- b. Ledger;
- c. Health insurance claim forms filed;
- d. Bill, ledgers, statements, correspondence, checks, receipts, or other materials relating to any health care facility or professional's billing to your facility for medical, radiological, or other health care services and/or facilities provided to or for Mr. Leopold, and any payment by your facility of any such charges or bills;
- e. Charge slips, charge tickets, billing memoranda and other supporting documentation relating to the charges or bills assessed by your facility to Mr. Leopold;
- f. List of explanations of billing codes which you use in your bills, ledgers, statements of fees, correspondence, checks, receipts or other materials concerning your billing system.

RESPONSE: Mayo objects to this request as overly broad, unduly burdensome, and disproportionate to the needs of the case. Mayo further objects to this request to the extent it purports to require Mayo to create documents.

Subject to and without waving the foregoing general and specific objections, Mayo refers Plaintiff to Noah Leopold's Mayo medical records, including the billing records therein.

REQUEST NO. 8: Consent forms: To the extent not contained in his medical record or provided in response to Requests 4 or 5, please produce all consent forms signed by Mr. Leopold.

RESPONSE: Mayo objects to this request as overly broad to the extent it seeks “all consent forms signed by Mr. Leopold,” regardless of whether they relate to the treatment in question.

Subject to and without waiving the foregoing general and specific objections, Mayo refers Plaintiff to Mayo’s responses to Request Nos. 4 and 5.

REQUEST NO. 9: Communications: Please produce all written or electronic communications, between or among any health care provider, that relate in any way to Mr. Leopold. This includes, but is not limited to, any communication sent via medical record platform, text message, pager, email, note, or other written or electronic communication.

RESPONSE: Mayo objects to this request as overly broad, unduly burdensome, disproportionate to the needs of the case, and as seeking information not relevant to the parties’ claims and defenses. Mayo further objects to this request to the extent it seeks protected health information or other information protected from disclosure by applicable law, contractual obligations, and/or obligations imposed on Mayo by non-Mayo entities, including without limitation CMS, UNOS, and TransMedics, Inc.

Subject to and without waiving the foregoing general and specific objections, Mayo refers Plaintiff to Noah Leopold’s Mayo medical records produced in response to Request No. 1. Following entry of a mutually-agreeable protective order, Mayo will produce additional documents not protected from disclosure that are responsive to this request and can be obtained through a reasonable search.

REQUEST NO. 10: Other records: Please produce all *other* records relating to Mr. Leopold other than those described above in your possession. This will

include all notes in any form, either written or electronic, taken by the nurses who cared for Mr. Leopold and pertaining to Mr. Leopold, recordings of any kind relating to Mr. Leopold, photographs relating to Mr. Leopold, or any other tangible, recorded or electronic thing which relates to Mr. Leopold.

RESPONSE: Mayo objects to this request as overly broad, unduly burdensome, disproportionate to the needs of the case, and to the extent it seeks information protected by the attorney-client privilege, work product doctrine, or peer review privilege, Minn. Stat. § 145.61, *et seq.* Mayo further objects to this request to the extent it seeks protected health information or other information protected from disclosure by applicable law, contractual obligations, and/or obligations imposed on Mayo by non-Mayo entities, including without limitation CMS, UNOS, and TransMedics, Inc.

Subject to and without waiving the foregoing general and specific objections, and following entry of a mutually-agreeable protective order, Mayo will produce documents not protected from disclosure that are responsive to this request and can be obtained through a reasonable search.

REQUEST NO. 11: Medical information or other written documents provided to Mr. Leopold or his family: Please produce copies of any written medical information or literature given to Mr. Leopold or Mr. Leopold's family by you or made available to them at your facility.

RESPONSE: Mayo objects to this request as overly broad and unduly burdensome insofar as it seeks all medical information or literature "available to them at [Mayo's] facility." Mayo further objects to this request as seeking information not relevant to the parties' claims and defenses, and to the extent it seeks information and documents equally available to both parties.

Subject to and without waiving the foregoing general and specific objections, Mayo refers Plaintiff to Noah Leopold's Mayo medical records

produced in response to Request No. 1. Discovery is ongoing, and Mayo reserves the right to supplement, revise, or amend this Response.

REQUEST NO. 12: OCS Heart data: Plaintiff understands that while a donor heart is being transported on the OCS Heart, system information is automatically stored internally on a TransMedics Data Card. The data on the card is then retrieved by the user at the end of the session. Please produce all data that was logged during the August 29 Donor Heart OCS Session. This data should include, but not be limited to, the following:

- All system error events
- All system operating alarm events
- Trend data for each perfusion parameter, in 2-minute intervals
- Blood gas sample values as entered by the user

RESPONSE: Mayo objects to this request as overly broad, unduly burdensome, and vague with regard to the meaning of “TransMedics Data Card.” Mayo also objects to this request as seeking information not relevant to the parties’ claims and defenses. Mayo further objects to this request to the extent it seeks protected health information or other information protected from disclosure by applicable law, contractual obligations, and/or obligations imposed on Mayo by non-Mayo entities, including without limitation CMS, UNOS, and TransMedics, Inc.

Subject to and without waiving the foregoing general and specific objections, and following entry of a mutually-agreeable protective order, Mayo will produce documents not protected from disclosure that are responsive to this request.

REQUEST NO. 13: OCS Heart data protocols: If the information requested above was not saved, or is no longer available, please provide a copy of all policies, procedures, protocols, directives, or other written guidance outlining Mayo’s usual practice for retrieving and maintaining data from OCS Heart Sessions.

RESPONSE: Mayo objects to this request as overly broad, unduly burdensome, and as seeking information not relevant to the parties' claims and defenses. Mayo also objects to this request as seeking information protected by the peer review privilege, Minn. Stat. § 145.61, *et seq.* Mayo further objects to this request to the extent it seeks protected health information or other information protected from disclosure by applicable law, contractual obligations, and/or obligations imposed on Mayo by non-Mayo entities, including without limitation CMS, UNOS, and TransMedics, Inc.

Subject to and without waiving the foregoing general and specific objections, Mayo states that it is not presently aware of any documents responsive to this request. Discovery is ongoing, and Mayo reserves the right to supplement, revise, or amend this Response.

REQUEST NO. 14: Photographs or other images of the OCS monitor: The OCS Heart has a wireless monitor that displays a variety of information, including alarms, organ parameters, status icons, a perfusion clock, graphical frames (which can be configured to show waveforms and trends), indicators, and other data. Please produce any photographs or other images that capture the display of the wireless monitor during any portion of the August 29 Donor Heart OCS Session.

RESPONSE: Mayo objects to this request as overly broad, unduly burdensome, disproportionate to the needs of the case, and vague. Mayo further objects to this request to the extent it seeks protected health information or other information protected from disclosure by applicable law, contractual obligations, and/or obligations imposed on Mayo by non-Mayo entities, including without limitation CMS, UNOS, and TransMedics, Inc.

Subject to and without waiving the foregoing general and specific objections, and following entry of a mutually-agreeable protective order, Mayo

will produce documents not protected from disclosure that are responsive to this request.

REQUEST NO. 15: Blood gas analyzer data: Plaintiff understands that during OCS Heart Sessions, a blood gas analyzer is utilized to periodically check blood gases, lactate, and electrolytes. To the extent not provided in response to another of these Requests, please provide a copy of all data that was collected about the August 29 Donor Heart using a blood gas analyzer.

RESPONSE: Mayo objects to this request as overly broad, unduly burdensome, disproportionate to the needs of the case, and vague. Mayo further objects to this request to the extent it seeks protected health information or other information protected from disclosure by applicable law, contractual obligations, and/or obligations imposed on Mayo by non-Mayo entities, including without limitation CMS, UNOS, and TransMedics, Inc.

Subject to and without waiving the foregoing general and specific objections, and following entry of a mutually-agreeable protective order, Mayo will produce documents not protected from disclosure that are responsive to this request.

REQUEST NO. 16: Blood gas analyzer data protocols: If the information requested above was not saved, or is no longer available, please provide a copy of all policies, procedures, protocols, directives, or other written guidance outlining Mayo's usual practice for retrieving and maintaining blood gas analyzer data from OCS Heart System Sessions.

RESPONSE: Mayo objects to this request as overly broad, unduly burdensome, disproportionate to the needs of the case, and as seeking information not relevant to the parties' claims and defenses. Mayo also objects to this request as seeking information protected by the peer review privilege, Minn. Stat. § 145.61, *et seq.* Mayo further objects to this request to the extent it seeks protected health information or other information protected from disclosure by applicable law,

contractual obligations, and/or obligations imposed on Mayo by non-Mayo entities, including without limitation CMS, UNOS, and TransMedics, Inc.

Subject to and without waiving the foregoing general and specific objections, Mayo states that it is not aware of any documents responsive to this request. Discovery is ongoing, and Mayo reserves the right to supplement, revise, or amend this Response.

REQUEST NO. 17: Communications: Please produce all written or electronic communications, between or among any health care provider, that relate in any way to the August 29 Donor Heart. This includes, but is not limited to, any communication sent via medical record platform, text message, pager, email, note, or other written or electronic communication.

RESPONSE: Mayo objects to this request as overly broad, unduly burdensome, disproportionate to the needs of the case, and to the extent it seeks information protected by the attorney-client privilege, work product doctrine, or peer review privilege, Minn. Stat. § 145.61, *et seq.* Mayo further objects to this request to the extent it seeks protected health information or other information protected from disclosure by applicable law, contractual obligations, and/or obligations imposed on Mayo by non-Mayo entities, including without limitation CMS, UNOS, and TransMedics, Inc.

Subject to and without waiving the foregoing general and specific objections, and following entry of a mutually-agreeable protective order, Mayo will produce documents not protected from disclosure that are responsive to this request.

REQUEST NO. 18: Suitability information: Please produce a copy of any and all information that was considered as part of your decision that the August 29 Donor Heart was a suitable organ for Noah Leopold.

RESPONSE: Mayo objects to this request as overly broad, unduly burdensome, and disproportionate to the needs of the case. Mayo further objects to this request to the extent it seeks protected health information or other information protected from disclosure by applicable law, contractual obligations, and/or obligations imposed on Mayo by non-Mayo entities, including without limitation CMS, UNOS, and TransMedics, Inc.

Subject to and without waiving the foregoing general and specific objections, Mayo refers Plaintiff to Noah Leopold's Mayo medical records produced in response to Request No. 1. Following entry of a mutually-agreeable protective order, Mayo will produce additional documents not protected from disclosure that are responsive to this request.

REQUEST NO. 19: PHM calculations: Please produce a copy of any and all calculations that were performed as part of assessing whether the August 29 Donor Heart was a suitable size for Noah Leopold. This includes calculations about the donor heart as well as calculations estimating Mr. Leopold's heart mass.

RESPONSE: Mayo objects to this request as vague insofar as "PHM" is not defined. Mayo also objects to this request as overly broad and unduly burdensome. Mayo further objects to this request to the extent it seeks protected health information or other information protected from disclosure by applicable law, contractual obligations, and/or obligations imposed on Mayo by non-Mayo entities, including without limitation CMS, UNOS, and TransMedics, Inc.

Subject to and without waiving the foregoing general and specific objections, Mayo refers Plaintiff to Noah Leopold's Mayo medical records produced in response to Request No. 1. Following entry of a mutually-agreeable protective order, Mayo will produce additional documents not protected from disclosure that are responsive to this request.

REQUEST NO. 20: PHM calculation methodology: If any of the PHM calculations performed as part of the assessment of the August 29 Donor Heart involved an app, website, algorithm, or other electronic or computer-based method, please provide a screenshot or other image allowing such app, website, algorithm, or other electronic or computer-based method to be identified.

RESPONSE: Mayo objects to this request as vague insofar as “PHM” is not defined. Mayo also objects to this request as overly broad and unduly burdensome. Mayo further objects to this request to the extent it seeks protected health information or other information protected from disclosure by applicable law, contractual obligations, and/or obligations imposed on Mayo by non-Mayo entities, including without limitation CMS, UNOS, and TransMedics, Inc.

Subject to and without waiving the foregoing general and specific objections, Mayo states that it is not aware of any documents responsive to this request. Discovery is ongoing, and Mayo reserves the right to supplement, revise, or amend this Response.

REQUEST NO. 21: OCS Heart training: Please produce a copy of all documents evidencing any training the following individuals received, at any time, regarding the OCS Heart:

- Dr. Salah Altarabsheh
- Dr. Gustavo Knop
- Michael Pick
- Any other Mayo agent or employee who was involved in the procurement or transport of the August 29 Donor Heart

This Request includes, but is not limited to, any training provided by TransMedics.

RESPONSE: Mayo objects to this request as overly broad, unduly burdensome, and disproportionate to the needs of the case.

Subject to and without waiving the foregoing general and specific objections, Mayo will produce the current CVs of Dr. Altarabsheh and Dr. Knop.

Mayo will also produce documents reflecting the OCS Heart training received by other Mayo employees that were involved in the procurement and transport of the August 29 Donor Heart.

REQUEST NO. 22: Employment contracts: Please produce a copy of any employment contracts in effect on August 29, 2023 for Dr. Salah Altarabsheh and/or Dr. Gustavo Knop.

RESPONSE: Mayo objects to this request as overly broad, unduly burdensome, and vague. Mayo also objects to this request as seeking information not relevant to the parties' claims and defenses based on Paragraphs 6 and 7 of Mayo's Answer to Plaintiff's Complaint. Mayo further objects to this request as seeking confidential employment information.

Subject to the foregoing general and specific objections, Mayo will not produce documents responsive to this request.

REQUEST NO. 23: Contracts or other agreements with TransMedics: Please produce a copy of any contracts or other agreements in effect on August 29, 2023 between Mayo and TransMedics.

RESPONSE: Mayo objects to this request as overly broad, unduly burdensome, and as seeking information not relevant to the parties' claims and defenses. Mayo further objects to this request to the extent it seeks information protected from disclosure by Mayo's contractual obligations.

Subject to and without waiving the foregoing general and specific objections, and following entry of a mutually-agreeable protective order, Mayo will produce a copy of its agreement with TransMedics, Inc., regarding the OCS Heart.

REQUEST NO. 24: Incident reports: If any of the events related to Mr. Leopold's failed August 29 attempted heart transplant were reported to any entity or agency – including but not limited to TransMedics, the FDA, the U.S. Department of Health & Human Service, the Minnesota Department of Health, the

Joint Commission, or any other entity or agency – please produce a copy of any documents evidencing such a report.

RESPONSE: Mayo objects to this request as overly broad, unduly burdensome, and as seeking information not relevant to the parties’ claims and defenses.

Subject to and without waiving the foregoing general and specific objections, Mayo states that it is not presently aware of any documents responsive to this request. Discovery is ongoing, and Mayo reserves the right to supplement, revise, or amend this Response.

Dated: June 17, 2024

DORSEY & WHITNEY LLP

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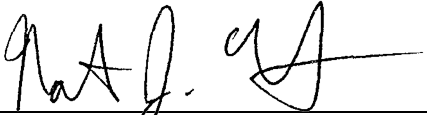
Rochester, MN 55905

CERTIFICATE OF SERVICE

I certify that on June 17, 2024, I caused a true and correct copy of **MAYO CLINIC'S OBJECTIONS AND RESPONSES TO PLAINTIFF'S FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS** to be served upon the counsel below via email:

Brandon E. Thompson
BET@ciresiconlin.com
Ciresi Conlin LLP
225 South Sixth Street, Suite 4600
Minneapolis, MN 55402

Dated: June 17, 2024



Nathan J. Ebnet